

TECHNICAL DATA SHEET



CERTIFICATION & STANDARDS

ISO 13485 certified manufacturer.
Class 1 Medical Device.
Health Canada registered medical device manufacturer.

STORAGE CONDITIONS

These gowns should be disposed of after each use.
Store under ambient temperature and dry condition.



FEATURES & BENEFITS

- Ultrasonically sealed over-the-head neck closure; allows safe and easy donning and doffing.
- Offers effective barrier performance for low fluid level procedures with AAMI PB70 Level 2 rating.
- Full back closure provides complete coverage for optimal protection.
- Elastic, thumbloop cuffs prevent sleeves from riding up.
- Non-woven SMMS fabric keeps wearers cool and comfortable.
- Flat belt on left hand side ensures a personalized fit.

RECOMMENDED USE

- Disposable SMMS Polypropylene Isolation Gown designed to protect health professionals and patients from cross infection. Protective ultrasonically sealed gown that meets AAMI PB70 Level II barrier performance for protective apparel.

PRODUCT DETAILS

Product Name:	Ritmed® AssureWear™ SMMS Isolation Gown
Product Type:	Single-use, non-sterile
Color:	Yellow
Sizes:	See Appendix 1
Quantity per Bag:	10
Country of Origin:	Myanmar

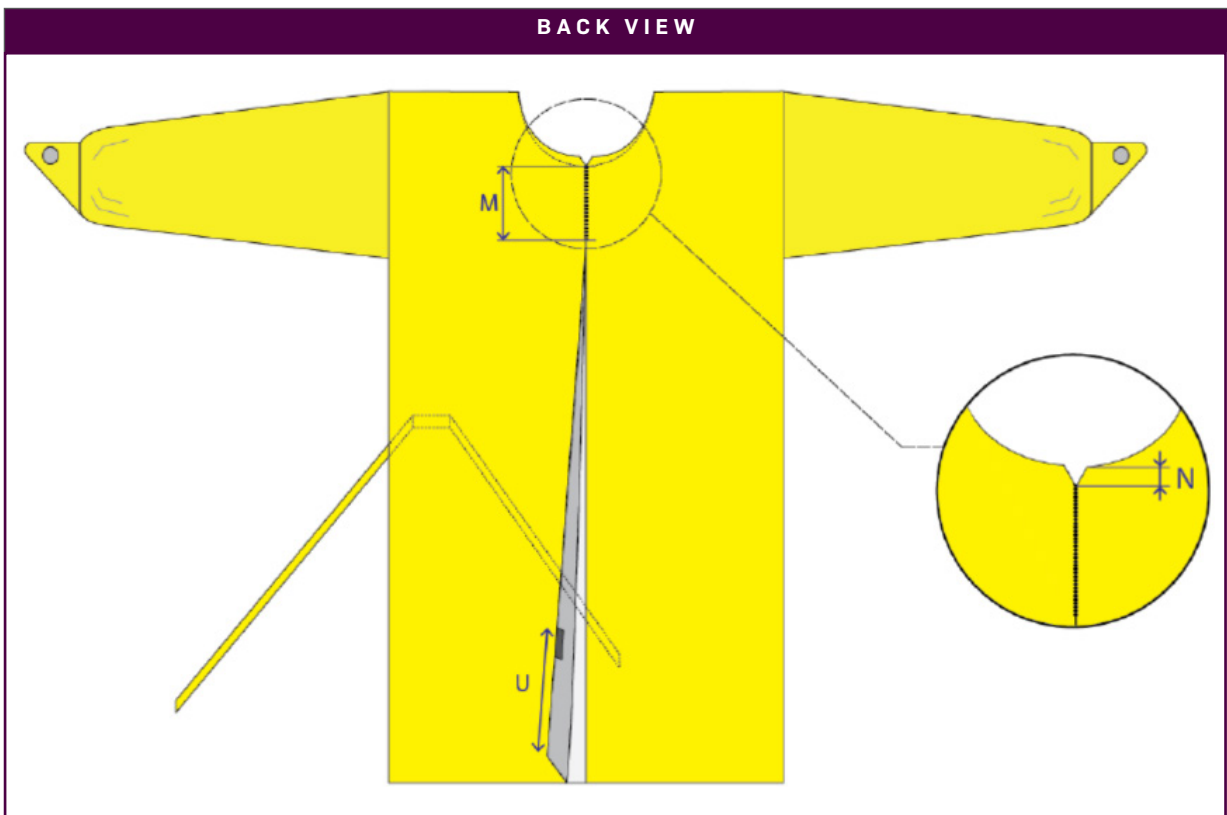
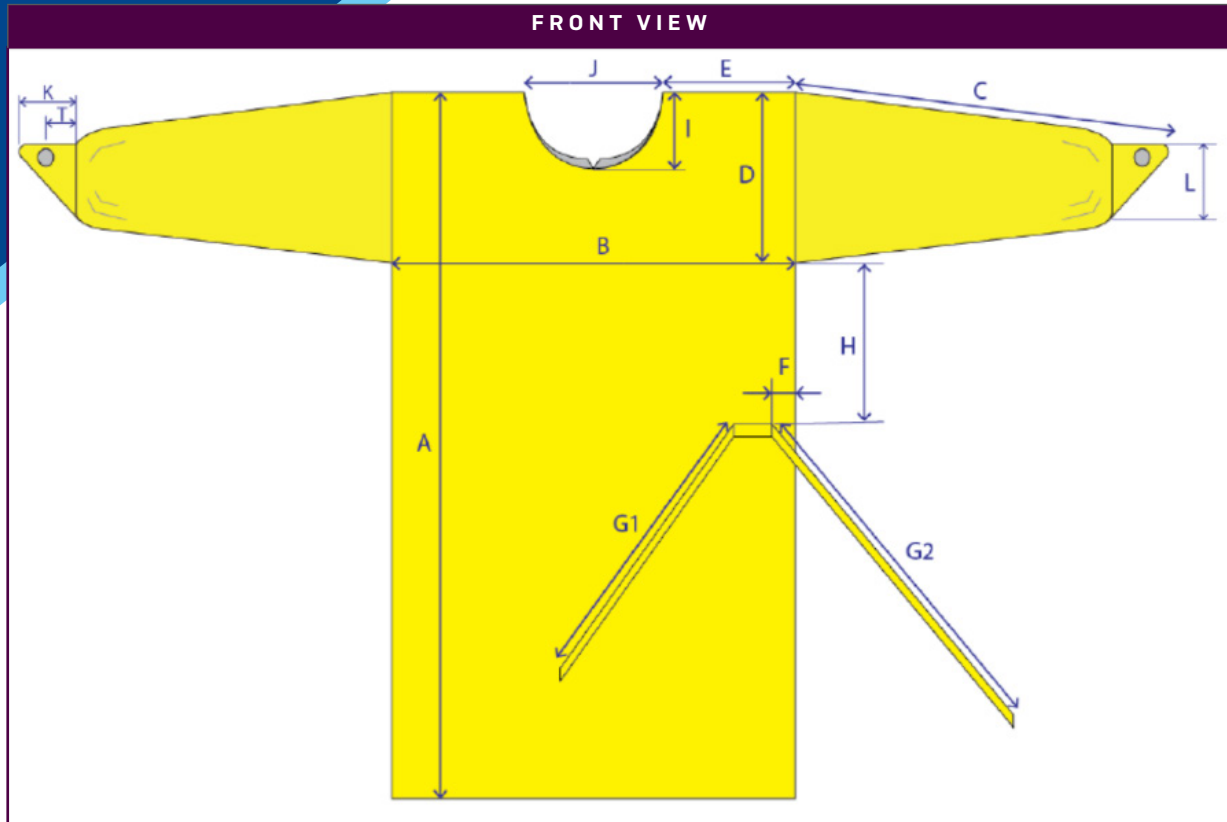
DONNING INSTRUCTIONS

- Perform hand hygiene before removing item from package.
- Select appropriate garment for intended use (length, coverage, fluid resistance, etc.)
- Protective apparel should not be worn in restrooms, personal offices or break rooms.

DOFFING INSTRUCTIONS

- Remove apparel immediately after use. Do not re-use.
- Perform proper hand hygiene after removing apparel to prevent cross-contamination.
- Turn garment inside out when removing to keep infectious material inside.
- Designate a safe receptacle in which to dispose of protective apparel after use.

GOWN SPECIFICATIONS			
CHARACTERISTIC		SPECIFICATION	
Material Composition		Spunbond Meltblown Meltblown Spunbond (SMMS) Polypropylene. Latex-free	
Description		Gown made of non-woven material with full back closure. Features flat belt, elastic cuffs (elastic does not go all around the cuff) with thumb loops available and Over-The-Head (OTH) neck closure made via an ultrasonically seal.	
Part of Gown		Dimension (cm)	
		Large	X-Large
A	Gown Length	112	129
	Open Gown Width	142	158
B	Underarm Width	71	79
C	Sleeve Length (Includes Thumb Loop)	65	65
D	Shoulder Height	30	32
E	Shoulder Width	23	26
H	Belt Position	20 cm below the left arm	20 cm below the left arm
F	Belt Position	7 cm toward the front	7 cm toward the front
G1	Belt Length Front	87	102
G2	Belt Length Back	93	108
	Total Belt Length	180	210
	Belt Width	5	5
I	Collar Depth	11 for front collar 11 for back collar	11 for front collar 11 for back collar
	Collar Trim Length	66	66
J	Collar Width	26	26
K	Wrist Height	10	10
T	Thumbloop Hole	5,5 from cuff seam to the center of the hole	5,5 from cuff seam to the center of the hole
	Thumbloop Hole Diameter	2,6	2,6
L	Cuff Width (Tightened)	8	8
L'	Cuff Width (Stretched)	14	14
M	Ultrasonic Seal on Back	13	13
N	V-Shaped Open on Back	1,5	1,5
U	Tag Position	22 - 25 from the bottom (Left side of back only)	22 - 25 from the bottom (Left side of back only)



Appendix 1 (List of items)

Item Code	Description	Packaging Information	Size	Color	Specific Attribute	Treatment	Marketed in USA as	Marketed in Canada as
A69977	Ritmed AssureWear SMMS Isolation Gown	10 Gowns/Bag, 10 Bags/Case, 100 Gowns/Case	Large	Yellow	Belt on the left side	Non-Sterile	Medical Device Class 1	Medical Device Class 1
A69978	Ritmed AssureWear SMMS Isolation Gown	10 Gowns/Bag, 10 Bags/Case, 100 Gowns/Case	X-Large	Yellow	Belt on the left side	Non-Sterile	Medical Device Class 1	Medical Device Class 1

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